UNITED STATES
PATENT AND
TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
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In re Application of	:
HARBERD et al	:
Serial No. 09/485,529	: DECISION ON PETITION
371 Filing Date: 1 March 2000	:
Attorney Docket No. 620-91	:

This letter is in response to the Petition under 37 CFR 1.144, filed 8 July 2002.

BACKGROUND

This application was filed on 1 March 2000, under 35 U.S.C. 371 as the national stage filing of PCT/GB98/02383, filed 7 August 1998, which claims priority to Great Britain serial number 9717192.02, filed 13 August 1997.

A review of the file history shows that original claims 1-53 were directed a polynucleotides which expressed in *Triticum aectivum* provide inhibition of growth, polynucleotide encoded by such, antibodies which bind to the polynucleotides, method of using the antibodies to obtain the polypeptide, primers specific for the polynucleotides and a method of using the primers to isolate (produce) the polynucleotide.

A preliminary amendment filed 15 June 2001 amended some claims' dependency to correspond with US practice and cancelled claim 47. A second preliminary amendment filed 26 June 2001 added SEQ ID Nos. to the claims to comply with the sequence requirements.

On 3 October 2001, the Office mailed Paper No. 12, which contained a five-way Restriction Requirement, dividing the claims into groups as follows:

Restriction to one of the following inventions is required under 35 U.S.C. § 121 and 372:

I. Claims 1-13 and 28-46, drawn to polynucleotide encoding Rht polypeptide or a cell comprising said polynucleotide and methods of transforming said cell.

II. Claims 48-50, drawn to a method of identifying a Rht polynucleotide using primers

III. Claims 51 and 53, drawn to isolated Rht polypeptide[1]

IV. Claim 52, drawn to an antibody

V. Claim 54 drawn to a method for obtaining or identifying a Rht polypeptide.

The Examiner explained that the technical feature linking Groups I-V appears to be that they all relate to genes for dwarfism in maize or wheat. However the examiner reasoned that such genes have already been disclosed in the prior art as evidenced by Harberd et al. Additionally the examiner stated that Chaing et al disclose the polypeptide of claim 14, so the technical feature is not a contribution over the prior art. The Examiner then states that the instant invention lacks unity of invention and restriction is set forth as it applies to U.S. practice.[2]

The Restriction Requirement also contained a request to restrict to one of the SEQ ID Nos. in Groups I-V, although no reasons to support this request were provided.

The Examiner concludes that

> Because these inventions I-V are distinct for the reasons given above and have acquired separate status in the art because of their different subject matter and fields of search, restriction for examination purposes as indicated is proper.[3]

In Paper No. 13, filed 3 December 2001, Applicants elected Group I, claims 1-46 and SEQ ID No. 104 for examination, with traverse.

Applicants pointed out some errors in the Group numbers: namely that at page 2, fifth line from bottom, reference was made to inventions IX and on page 2, fifth line of first full paragraph and one page 3, line 6, reference is made to Groups I-VIII. Applicants also pointed out that claims 14-27 were not included in any Group and that they should be included in Group I. The election contained an extensive traverse, the bulk of which is included in the petition under review and will be considered below. Applicants also added two new claims 55-56 drawn to the invention of Group I.

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[1] Claim 53 belonged with claim 52 in Group IV since it is directed to a polypeptide which includes the antigen binding site of the antibody of claim 52.

[2] This application is filed as a 371 national stage of a PCT application. As such, Unity of Invention applies to this application, even if the technical feature linking several groups is purportedly not a contribution over the prior art.

[3] This conclusion is not in keeping with the Restriction Requirement, because the action failed to discuss the classification of the groups or to elaborate on any different fields of search.

On 6 February 2002, the Office mailed a non-final action as Paper No. 14. Applicants' election and traversal was acknowledged. The Examiner agreed that Group I encompasses claims 1-49 and that all the claims were divided up among Groups I-V in the Restriction Requirement. The Examiner also agreed to examine claims in Group I drawn to SEQ ID No. 104 and SEQ ID No. 7 and their encoding polynucleotides 105 and 14, encompassing claims 1-9,14-16, 26-46 and 55-56.[4]

The Examiner conceded that none of the references teaches or suggests disclosed Rht polynucleotides/polypeptide sequences, still the Restriction Requirement was deemed proper in view of a variety of US practice considerations, including distinctness, independence, search burden.[5] The Restriction Requirement was made FINAL.

Claims 10-13, 17-25 and 48-54 were withdrawn from examination as being directed to non-elected inventions. Claims 1-3, 6-9, 14-16 were rejected under 35 U.S.C. 112, second paragraph for indefiniteness. Claims 1-2, 6-9, 14-16, 30-31 and 55-56 and dependent claims 28-29, 32-45 were rejected under 35 U.S.C. 112, first paragraph for lacking full scope of enablement. Claims 1-2, 6-9, 14-16, 28-46 and 55-56 were rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not adequately described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed had possession of the claimed invention. Claims 1-9, 14-16, 26-46 and 55-56 were deemed free of the prior art. Claims 4-5 and 26-27 were considered allowable.

On 8 July 2002, applicants filed an amendment to the specification and claims, canceling claims 2, 7-9, 16, 30, 31, 55 and 56 and amending claims 1, 3, 6, 14, 15, 32, 33, 36-42, 45, and 46. Applicants also filed this petition.

On 27 September 2002, Special Program Examiner Burke contacted applicants representative and invited them to correct certain informalities with claims 10-13 (depend upon canceled claims) and 48-50 and 54 (improper multiple dependent claims) via an amendment sent by facsimile to (703)-305-7939.

On 3 October 2002, applicants faxed in an amendment to claims 48, and 54.

DISCUSSION

The application, file history and petition have been considered carefully. The petition presents two concerns:

(1) a request to have the restriction requirement between Groups I-V withdrawn.

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[4] It is noted that Group I is not directed to polypeptides. Group I is directed to the polynucleotides encoding SEQ ID Nos. 7 and 104, including polynucleotides with SEQ ID No. 14 and 105. SEQ ID No. 7 is an amino acid sequence 623 residues in length and is encoded by SEQ ID No. 14. SEQ ID No. 104 is an amino acid sequence fragment of SEQ ID No. 104, and is 17 residues in length and is encoded by SEQ ID No. 105.

[5] None of which apply to this application filed under 35 U.S.C. 371 as a national stage from a PCT application.

(2) a request that the requirement for the election of sequences be withdrawn.

Each concern will be addressed in turn.

Applicants are correct that the instant application represents the national stage filing of PCT/GB98/02383 and that Unity of Invention standards apply for any restriction of inventions in this application.

The Petition explains that the Rht phenotype is a dwarf phenotype in wheat and is known in the prior art. A corresponding phenotype characterized in maize as D8/D9 is also known in the prior art. Applicants present that the special technical feature is the nucleotide sequences which are responsible for the Rht dwarf phenotype in other plants, which phenotypes are gibberellin insensitive. According to PCT Rule 13.2, the special technical feature means those technical features that define a contribution which each of the claimed inventions, when considered as a whole, makes over the prior art. On this point the examiner has agreed: the prior art does not each or suggest the invention in the claims under examination. See Paper No. 14, page 2-3, bridging paragraph. Thus applicants and examiner have agreed that the special technical feature of Group I is the polynucleotide molecules which are responsible for the Rht dwarf phenotype in other plants, which phenotypes are gibberellin insensitive.

MPEP 1850 and the PCT Administrative Instructions, Annex B explain which Combinations of Different Categories of Claims may be permitted under PCT Rules.

> In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product.

In this application, the first product is the polynucleotide molecule (Group I, minimally claims 1, 3-6, 14-15, 26-29, 32-38, 42, 43). The first method of use for the polynucleotide molecule is in the transformation of cells to make plant cells or plant (Group I, claims 39-41, 44-46). The first method of making the polynucleotide molecule is the method of identifying or isolating the polynucleotide (Group II, claims 48-50).

In the instant application, Group I already includes the first product and the first method of using that product. Group II recites the first method of making the first product. Applicant is correct in requesting the rejoinder of Group II with Group I. Claims 48-50 are drawn to the first method of making the polynucleotide. Claims 48-50 were incorrectly placed in a different group in the restriction requirement and will be rejoined with Group I.

The Petition requests also the rejoinder of Groups III, IV and V with Group I because these relate to the isolated Rht polypeptide, antibody which binds the polypeptide and methods of identifying Rht polypeptide. This reasoning is not persuasive for the following reasons.

The polypeptide of Group III does not share a special technical feature with the polynucleotide of Group I. According to the PCT Administrative Instructions, for molecules to be of similar nature, they need to share a common core structure and a common property or activity. Groups I and III do not meet the criteria of Markush Practice in PCT Administrative Instructions, Annex B because a DNA molecule and a protein molecule share neither common structure nor common function. Unity of Invention is lacking between Groups I and III.

Nor does the relationship of polypeptides of Group III and the polynucleotides of Group I conform with Example 17 of the PCT Administrative Instructions. In Example 17, there exists a one-to-one interrelationship between the Protein X and the DNA molecules which encode Protein X. Given a particular amino acid sequence, one can identify all of the open reading frames which encode that molecule, due to degeneracy of the DNA codon. The instant claims are written in the opposite format: DNA X and polypeptide encode by DNA X. In view of the presence of six different open reading frames, different potential start sites, different splice sites, etc, one cannot identify all of the protein molecules which will be encoded by DNA X. A second importance distinction between the instant claims and those in Example 17, the instant claims are not directed to a single molecule but encompass a family of molecules which are defined by a minimal structure. For these reasons, there is no shared technical feature between the polynucleotides of Group I and the polypeptides of Group II. Thus applicants' request to have Group III examined concurrently with Group I is denied.

A similar analysis shows that the antibodies of Group IV do not share a technical feature in common with either the polypeptide of Group III nor with the polynucleotide of Group I. There is no shared property or activity in common with the antibody, the polypeptide it binds to and the polynucleotide which encodes the polypeptide. Nor is there a shared common core structure between the antibody, the polypeptide it binds to and the polynucleotide which encodes the polypeptide. For these reasons, the antibody, polypeptide and polynucleotide do not meet the criteria of similar nature set forth in PCT Administrative Instructions, Annex B, "Markush Practice." Applicants' request to have Groups III and IV examined with Group I is denied.

Finally, with regards to the request to rejoin Group V, claim 54, with Group I, it is noted that claim 54 is directed to a method of using the second product, the polypeptide of Group III. The PCT Administrative Instructions, Annex B, Categories of Invention makes it clear that a method of using the second product does not have unity of invention with the first product. The restriction between Groups I and V is proper.

Turning now to applicants' request to have all the claims directed to polypeptide sequences examined together, it is noted that the withdrawn claims 10-13, 17-25, and 48-50 directed to the non-elected sequences are dependent from and therefore necessarily narrower in scope than the independent claims 1, 6 and 14. Independent claims 1, 6 and 14 have already been examined and found free of the prior art. The Office cannot establish a burden of search of the additional sequences because the claims are drafted in a manner that the sequences are required together to describe the invention. The

sequences are not claimed in the alternative as separate inventions. Applicants are correct that in this application, restriction to a single sequence is improper.

DECISION

The petition is **GRANTED-IN-PART** for the reasons set forth above as follows:

> The Restriction Requirement between Groups I, III, IV and V is maintained.
> The Restriction Requirement between Groups I and Group II has been withdrawn.
> The restriction requirement to a single sequence has also been withdrawn.
> Claims 1, 3-6, 10-15, 17-29, 32-46, 48-50 are under examination.
> Claims 51-54 remain withdrawn as being directed to the non-elected invention.

There is no fee for the filing of this petition. A credit of $130.00 will be deposited to Applicants' Deposit Account 14-1140.

The Office will enter the amendment filed 3 October 2002 to correct the dependency of claims 48 and 54. The application will then be forwarded to the examiner for action consistent with this decision.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, Washington DC 20231 or by telephone at (703) 308-7553 or by facsimile transmission at (703) 305-7230.

John Doll
TC1600 Group Director